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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,880	06/03/2004	David M. Richlin	RICHP001US	9853

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EXAMINER	
NOLAN, JASON MICHAEL	

ART UNIT	PAPER NUMBER
1626	

NOTIFICATION DATE	DELIVERY MODE
09/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/709,880	RICHLIN ET AL.	
	Examiner	Art Unit	
	JASON NOLAN	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-150* is/are pending in the application.

4a) Of the above claim(s) *66-150* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☒ Claim(s) *2-65* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/3/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to Applicant's Response to Election/Restriction, filed June 3, 2009. Claims 1-150 are pending in the instant application; of which Claim 1 is currently amended.

Information Disclosure Statement

Applicants' information disclosure statement (IDS), filed on June 3, 2009 has been considered. Please refer to Applicants' copy of the 1449 submitted herein.

Response to Restriction

Applicants' election with traverse of Group I: Claims 1-65 is acknowledged. The Examiner also acknowledges the election of species: a preparation containing phenylephrine, lecithin, and ketoprofen.

Applicant's traversal alleges that Examiner has not met the burden of providing an example that shows that the instant product and process are distinct inventions. The Examiner cited the product Lidoderm as being useful for the treatment of chronic pain. *See* Office Action, mailed 05/15/09, p. 3. The instant "method of use" Claims 67-150 all depend from independent method Claim 66, which states: "A method of topically delivering and localizing therapeutic agents, comprising the steps of: using a vasoconstrictor for retarding vascular dispersion of a therapeutic agent; in combination with using a penetration enhancer for facilitating penetration of said vasoconstrictor and said therapeutic agent through a patient's skin." (Emphasis added).

Applicants have pointed out that Lidoderm is not a suitable example for the "process of using as claimed" because Lidoderm does not appear to contain any penetration enhancer. However, Lidoderm contains urea, which is known to have "modest penetration enhancing activity." *See* Williams *et al. Advanced Drug Delivery Reviews* 2004, 56, 603-618; specifically p. 612. Further, Applicants state the Lidoderm fails to contain a vasoconstrictor. Assuming arguendo that Lidoderm fails to contain a vasoconstrictor, it follows that Lidoderm also fails to be an example based on the "process of using [the product] as claimed." As a result, the burden is now on the Examiner to support a viable alternative or withdraw the restriction requirement.

The Examiner points out that a viable alternative exists in US 7,273,887 ("the '887 patent. The '887 patent teaches the "process of using [the product] as claimed" – specifically, the method of Claim 66 with specific limitations (underlined *supra*).

For instance, Claim 11 of the '887 patent recites a method for reducing pain comprising the step of applying a formulation to the area of the skin to be treated, wherein the formulation in Claim 1 of the '887 patent comprises a therapeutic agent and a penetration enhancer. The '887 patent states, "It is also contemplated that the present invention can optionally include a vasoconstrictor." *See* col.3, ll. 26-30. Inasmuch, Claim 10 recites a formulation comprising a vasoconstrictor, a penetration enhancer, and a therapeutic agent (the underlined limitations identified *supra*).

Applicants traverse and objection to Examiner's redaction of an earlier allowance of Claims 9-12, 17-21, 23-65, & 66-150 without relying on any prior art under 35 USC 102 or 103 is acknowledged. The Examiner relied on the '887 patent for said redaction

because the teachings of the '887 patent are anticipatory to at least Claim 66, shown above. Thus, redacting the allowance of Claim 66, in light of this prior art of record, is a service to both Applicant and the public because doing so complies with the Office's goal of issuing valid and enforceable patents.

For the reasons provided above, Group I: Claims 1-65 and Group II: Claims 66-150, identified in the Office Action, mailed May 15, 2009 have been shown to be patentably distinct (i.e., the process for using the product as claimed can be practiced with another materially different product). Further, restriction is proper because the inventions of Group I and II are distinct and there would be a serious search and examination burden if restriction were not required because, i.e., the inventions have acquired a separate status in the art (product vs. method of use) in view of their different classification (class 424 vs. class 514). Applicant is reminded of the right of rejoinder identified on pp. 6-7 of said Office Action.

As a result of Examiner's Restriction Requirement and Applicant's election of Group I: Claims 1-65, the non-elected Group II: Claims 66-150 is withdrawn herein from further consideration. Until Group I is allowable, Group II is ineligible for rejoinder.

Examination of Elected Species/Group

As pointed out on page 4 of the Restriction Requirement/Election of Species, mailed May 15, 2009, examination will begin with the elected species. As per MPEP 803.02, if the elected species is found to be unpatentable, the provisional election will be given effect and all other claims to species will be withdrawn from consideration. If

the elected species is found to be allowable, the search will be expanded by the Examiner to consider additional species and subgenera within the generic formula until: 1) An art rejection can be made, or 2) The genus claim is found to lack unity of invention, or 3) The claims have been searched in their entirety.

Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration. . . . On the other hand, should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a non-elected species, the Markush-type claims shall be rejected and claims to the nonelected species held withdrawn from further consideration.

In this case, the elected species comprises a preparation containing phenylephrine as the vasoconstrictor, lecithin as the penetration enhancer, and ketoprofen (a non-steroidal anti-inflammatory drug used in horses and other equines) as the therapeutic agent.

Response to Amendment and Argument

Applicant's argument and amendment filed April 7, 2008 have been fully considered but are not persuasive. Specifically, Applicant argues that the instant claims, as currently amended to recite: "said therapeutic agent is separate and distinct from said vasoconstrictor itself;" are distinct from the '603 patent because the '603 patent utilizes the combination of a vasodilator and a vasoconstrictor, wherein said vasodilator and vasoconstrictor are themselves the active therapeutic agents and work in synergistically in treating erectile dysfunction.

Erectile dysfunction, or impotence, is defined as both 1) the inability to achieve an erection, or 2) to maintain an erection. Thus, Applicant's remark that the vasoconstrictor is itself a therapeutic agent is correct because it treats the latter by restricting blood flow out of the penis. The vasodilator treats the former by inducing an erection. For this reason, Applicant's interpretation is reasonable; however, the claims as written still fail to eliminate the '603 patent as prior art. The claim limitations require a vasoconstrictor, a penetration enhancer, and a therapeutic agent, wherein said therapeutic agent is separate and distinct from said vasoconstrictor.

While the vasodilator and vasoconstrictor may be fact work synergistically, papaverine and epinephrine are still "separate and distinct." For instance, papaverine may be used without epinephrine via injection. *See* col. 3, ll. 23-26. The '603 patent still fulfills the claim limitations because Example 5, for example, is an ointment comprising papaverine (therapeutic agent), epinephrine (vasoconstrictor), and dimethylsulfoxide (penetration enhancer).

As identified supra, the search will begin with the elected species. The elected species comprises a preparation containing phenylephrine as the vasoconstrictor, lecithin as the penetration enhancer, and ketoprofen (a non-steroidal anti-inflammatory drug used in horses and other equines) as the therapeutic agent. The search did not result in a prior art rejection. The closest prior art was US 5,434,144, which teaches methods of treating skin wrinkles and mentions penetration enhancers (col. 8, ll. 62-68 – col. 9, ll. 1-27), including lecithin (col. 8, l. 12), as well as therapeutic agents such as non-steroidal anti-inflammatory drugs (col. 12, ll. 44-68) and specifically ketoprofen (col. 12, l. 58). However, the patent does not disclose vasoconstrictors.

For this reason, the search was expanded until a prior art rejection could be made (*infra*).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US 5,059,603 ("the '603 patent"). The instant application, as currently amended, still fails to distinguish the '603 patent. For instance, Example 5 in column 9 is an ointment comprising papaverine (therapeutic agent), epinephrine (vasoconstrictor), and

dimethylsulfoxide (penetration enhancer). Therefore, all of the claim limitations have been met.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by WO01/41550. For convenience, US 7,273,887 ("the '887 patent") is referred to herein. Recited in Claim 11 of the '887 patent is a method for reducing pain comprising the step of applying a formulation to the area of the skin to be treated, wherein the formulation in Claim 1 of the '887 patent comprises a therapeutic agent and a penetration enhancer. The '887 patent states, "It is also contemplated that the present invention can optionally include a vasoconstrictor." *See* col.3, ll. 26-30. Inasmuch, Claim 10 recites a formulation comprising a vasoconstrictor, a penetration enhancer, and a therapeutic agent (the underlined limitations identified *supra*).

Claim Objections

Claims 2-65 are objected to for containing non-elected subject matter. Appropriate correction is required.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason M. Nolan whose telephone number is (571) 272-4356 and e-mail is Jason.Nolan@uspto.gov. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are

unsuccessful, the examiner's supervisor, Joseph M^{c}Kane can be reached on (571) 272-0699. The USPTO fax number for applications is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system, (either Private PAIR or Public PAIR). Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. For questions on Private PAIR system, contact the Electronic Business Center at (866) 217-9197.

/Jason M. Nolan/

Examiner, Art Unit 1626

/Rebecca L Anderson/

Primary Examiner, Art Unit 1626